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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Appellant(s): Wolfgang R. STREBER et.al.

940224

Diana Hamlet-King
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 26 August of 1992.

(1) Status of claims.

The statement of the status of claims contained in the brief is incomplete.

A complete statement of the status of the claims is as follows:

This appeal involves claims 17, 18, 23, 32, 33, 35, 42, 43, and 45 to 53.

Claims 18, 35 and 46 have been amended subsequent to the final rejection.

Claims 10 to 16, 19 to 22, 24 to 31, 34, 36 to 41, and 44 have been withdrawn from consideration as not directed to the elected invention.

Claims 1 to 9 have been canceled.

(2) Status of Amendments After Final.

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(3) Summary of invention.

The summary of invention contained in the brief is correct.

(4) Issues.

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: .

The rejection of claims 18 and 35 under 35 U.S.C. 112, second paragraph, because they depend from a canceled claim, is

withdrawn in view of their amended status.

(5) Grouping of claims.

All claims stand or fall together.

(6) Claims appealed.

The copy of the appealed claims contained in the Appendix to the brief is correct.

(7) Prior Art of record.

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

U.S. Pat. No. 4,349,629, Carey et.al., Sept. 14, 1982.

Amy, S.A., et.al., "Characterization of Aquatic Bacteria and Cloning of Genes Specifying Partial Degradation of 2,4-Dichlorophenoxyacetic Acid." Applied and Environmental Microbiology, vol. 49, no. 5 (May 1985), pp. 1237-1245.

Comai, L., et.al., "Expression in plants of a mutant aroA gene from Salmonella typhimurium confers tolerance to glyphosate." Nature, vol. 317 (October 24 1985), pp. 741-744.

Beguin, P., et.al., "Sequence of a Cellulase Gene of the Thermophilic Bacterium Clostridium thermocellum." Journal of Bacteriology, vol. 162, no. 1 (April 1985), pp. 102-105.

(8) New prior art.

No new prior art has been applied in this examiner's answer.

(9) Grounds of rejection.

The following ground(s) of rejection are applicable to the appealed claims.

Claims 23, 32, 33, 35, 42, 43, 45, 48, and 51 to 53 stand rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to a 2,4-D

monooxygenase gene isolatable by the manner disclosed in the instant specification or having some functionally defined degree of sequence similarity to the gene described in the instant specification. The specification is not enabling for the isolation or production of any 2,4-D monooxygenase gene from any source.

Claims 46 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is indefinite because it is drawn to "a DNA sequence hybridizable therewith" which places no functional or size limits on said DNA and is inherently indefinite. The conditions of hybridization (stringency) are not specified even though these conditions constitute a critical limitation of such a claim. Any DNA molecule is capable of hybridizing to any other DNA molecule under appropriate conditions. Because of this characteristic, artisans must routinely employ denaturing agents such as high temperatures (relative to normal biological systems) and formamide in nucleic acid hybridization procedures to control the amount of non-specific hybridization that occurs and to provide a minimal degree of nucleotide sequence similarity that is required of a nucleic acid before it will hybridize to the nucleic acid in question. Absent such conditional limitations, claim 46 is indefinite.

Claims 17, 18, 23, 32, 33, 35, 42, 43, and 45 to 53 are rejected under 35 U.S.C. § 103 as being unpatentable over the Amy et.al. and Beguin et.al. references in view of the Comai et.al. publication. These claims are drawn to a recombinant gene comprising a heterologous plant promoter coupled to a sequence encoding a 2,4-D monooxygenase, a vector containing this gene, and a plant containing such a vector. The Amy reference clearly describes the construction of the plasmid PSA122 containing a 2,4-D monooxygenase gene from an aquatic bacteria that is phenotypically similar to Alcaligenes eutrophus. The 2,4-D monooxygenase gene described in the Amy reference differs from that claimed in the instant invention in the degree of definition and refinement of the cloned gene and the claimed use. The Beguin reference is used here to show that the subcloning and sequencing of a cloned gene was a routine procedure in the art of molecular biology at the time the instant invention was made. In light of the Amy and Beguin references one of ordinary skill would have found an isolated gene encoding a 2,4-D monooxygenase from an aquatic bacteria to be fairly taught at the time of the instant invention. These references do not teach the expression of this gene in a plant as claimed. The Comai et.al. publication shows that the isolation of a potential herbicide resistance gene from a bacteria and the subsequent insertion of that gene, coupled to an appropriate plant promoter, into the chromosome of a plant so that plant would be rendered resistant to the

detrimental effects of said herbicide was known in the art prior to the time the instant invention was made. To use the methods as described in the Comai reference to transfer the 2,4-D monooxygenase gene described in the Amy reference into a plant to render that plant resistant to the detrimental effects of 2,4-D would have been obvious to one of ordinary skill at the time of the instant invention. The Comai reference clearly indicates that the critical parameters involved in transferring into and expressing a bacterial gene in a plant genome were well known at the time the instant invention was made.

(10) New ground of rejection.

This Examiner's Answer does not contain any new ground of rejection.

(11) Response to argument.

The rejection of claims 23, 32, 33, 35, 42, 43, 45, 48, and 51 to 53 under 35 U.S.C. § 112, first paragraph, has been traversed on the grounds that "the disclosure provides ample enablement for isolation of 2,4-D monooxygenase [genes] from a large number of sources and by several methods". This is true, but, these claims read on all 2,4-D monooxygenase genes from any and all sources for which adequate enablment is lacking. The specification is limited to methods applicable only to genes able to hybridize to those sequences disclosed in the instant specification under a defined set of conditions or, at best, those sequences isolatable from bacteria able to use 2,4-D as a

sole carbon source, which would undoubtedly exclude organisms able to use 2,4-D as an ancillary carbon source.

This rejection is maintained because the instant disclosure only provides a single example of the isolation of a single DNA encoding a 2,4-D monooxygenase from a single organism in which this DNA was disclosed by the prior art to be plasmid encoded. This example describes the isolation of a plasmid encoded gene from one gram negative bacteria by cloning that gene into another gram negative bacteria followed by detection of a functional gene product. This limited disclosure certainly does not describe the isolation of a DNA encoding any 2,4-D monooxygenase from a non-bacterial host which would not be expected to be functionally expressed in the disclosed host and whose isolation would therefore not be enabled by the instant specification.

The rejection of claims 17, 18, 23, 32, 33, 35, 42, 43, and 45 to 53 under 35 U.S.C. § 103 as being unpatentable over the Amy et.al. and Beguin et.al. references in view of the Comai et.al. publication has been traversed on the grounds that the Comai et.al. publication did not teach the expression of an exogenous bacterial gene in a plant. Applicant does not appear to dispute the obviousness of an isolated DNA encoding a 2,4-D monooxygenase and the declaration filed by Wolfgang R. Streber under 37 C.F.R. § 1.132 does not address this issue.

The issue in dispute is whether or not the incorporation of such a DNA into a plant for the purpose of making that plant less

susceptible to the action of the herbicide 2,4-D was made obvious by the Comai et.al. publication prior to the instant invention. The Comai et.al. publication shows that the isolation of a potential herbicide resistance gene from a bacteria and the subsequent insertion of that gene, coupled to an appropriate plant promoter, into the chromosome of a plant so that plant would be rendered resistant to the detrimental effects of that herbicide was known in the art prior to the time the instant invention was made. This reference clearly shows that the critical parameters involved in transferring into and expressing a bacterial gene into a plant genome were well known prior to the instant invention. The argument that the bacterial gene described in the Comai et.al. reference has a host cell homologue is not relevant since the that homologue is not structurally related to the bacterial gene or its product. An artisan would certainly not expect the functional expression of the tobacco aroA homologous gene in a Salmonella typhimurium host simply because that host has a functionally homologous gene. This is why the presence of a host cell homologue of a heterologous gene would not have been used as an indication of whether the heterologous gene could have been successfully expressed in that host absent evidence of structural relatedness. One of ordinary skill wishing to predict the probably of obtaining the expression of a gene from a specific source organism in a specific heterologous host organism would have depended upon the prior art

applicable to the particular source/host system as a guide. In the instant case, an artisan would have known that a structural gene from a gram negative bacterial source had been successfully expressed in a plant system prior to the time of the instant invention and would have reasonably expected that any other bacterial genes could also be expressed in a plant, absent unexpected results.

The argument that one could not predict if a plant would be protected from the 2,4-dichlorophenol that is produced from 2,4-dichlorophenoxyacetic acid by the product of the claimed gene is not persuasive. An artisan would have known, prior to the instant invention, that the 2,4-dichlorophenol is less toxic to a host plant than 2,4-dichlorophenoxyacetic acid and therefore would have expected the presence of the claimed gene product to increase the tolerance of a susceptible host cell for 2,4-dichlorophenoxyacetic acid.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

John D. Ulm

ROBERT J. HILL, JR.
PRIMARY EXAMINER
ART UNIT 1812